

## Corporate Medical Policy

# Bone Marrow Transplant for Acute Lymphocytic Leukemia

**File Name:** bone\_marrow\_transplant\_for\_acute\_lymphocytic\_leukemia  
**Policy Number:** SUR6090.3  
**Origination:** 2/2001  
**Last Review:** 3/2008  
**Next Review:** 3/2010

### Description of Procedure or Service

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This policy addresses high-dose chemotherapy with [hematopoietic](#) stem-cell support as a treatment of acute lymphocytic leukemia. Bone marrow transplants typically include high-dose chemotherapy (HDC).

"High-dose chemotherapy" (HDC) involves the administration of [cytotoxic agents](#) for the treatment of cancer. It uses doses several times greater than the standard therapeutic dose. In some cases, whole body or localized radiotherapy is also given and is included in the term HDC. The rationale for HDC is that many [cytotoxic agents](#) act according to a [steep dose-response curve](#). Thus, small increments in dosage will result in relatively large increases in tumor cell kill. Increasing the dosage also increases the incidence and severity of adverse effects related primarily to bone marrow [ablation](#) (e.g., [opportunistic](#) infections, hemorrhage, organ failure).

Various techniques have been developed to counter the [myelosuppressive](#) effects, and secondary susceptibility to infections of HDC regimens. The main technique is the infusion into the patient of [hematopoietic stem cells](#) to repopulate the bone marrow. [Hematopoietic stem cells](#) are primitive cells capable of replication and formation into mature blood cells. [Stem cells](#) can be [harvested](#) from three sources:

1. Bone marrow cells: Bone marrow [stem cells](#) can be harvested from a related or unrelated donor.
2. Peripheral [stem cells](#): [Stem cells](#) may be harvested from the peripheral blood circulation. This may involve several pheresis procedures. Pheresis involves withdrawing blood from a donor in which a portion containing [stem cells](#) is separated and retained with the remainder retransfused back to the donor.
3. [Umbilical cord](#) blood: Blood harvested from the [umbilical cord](#) and [placenta](#) shortly after the delivery of neonates contains [stem cells](#). Although cord blood is an [allogeneic](#) source, these [stem cells](#) are associated with a lower incidence of rejection or graft versus host disease.

When [harvested](#) from and infused back into the same patient, [stem cells](#) are referred to as [autologous](#). [Stem cells harvested](#) from a healthy, [histocompatible](#) donor and infused into a patient are referred to as [allogeneic](#).

Acute Lymphocytic Leukemia (ALL) occurs in multiple forms that vary with regard to cellular morphology. Although adult and childhood forms of ALL vary, there is considerable overlap, especially among late adolescents and young adults. Consequently, there is not a clear age separation that divides the adult and childhood forms. As a consequence of the differences between cellular morphology in adult and childhood ALL, they respond differently to treatment and vary in their risk for relapse once remission is achieved. For example, childhood ALL is a highly curable disease, with long-term survival rates ranging from 60% to 85%. Similar therapy regimens have had less favorable outcomes in adult ALL. Approximately 65% to 90% of those with adult ALL achieve a complete remission, but only 20% to 30% become long-term survivors.

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BCBSNC will provide coverage for Bone Marrow Transplant, high dose chemotherapy and stem cell support for Acute Lymphocytic Leukemia (ALL) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services for Life-Threatening Conditions.

### Benefits Application

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Please refer to certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

There may be certificates which exclude benefits for transplantation or for specific diagnoses.

Services for or related to the search for a donor are not covered.

### When Bone Marrow Transplant for Acute Lymphocytic Leukemia is covered

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**Note: The clinical indications and discussion of Bone Marrow Transplant for Acute Lymphocytic Leukemia is complex and technical. If you have any questions concerning this treatment, please talk with your physician.**

#### A. Children

1. High dose chemotherapy with [allogeneic](#) or [autologous](#) stem cell support may be considered medically necessary as a treatment of childhood ALL in first complete remission but at high risk of relapse. High risk of relapse following initial complete remission is indicated by the presence of at least **one** of the following:
  - a. Age greater than 15 years
  - b. Leukocyte count greater than  $10 \times 10^9/L$
  - c. Extramedullary disease, particularly CNS
  - d. Chromosomal abnormalities, including Philadelphia chromosome
  - e. Failure to achieve a complete remission within 6 weeks of the start of induction therapy.
2. High dose chemotherapy with [autologous](#) or [allogeneic](#) stem cell support may be considered medically necessary as a treatment of childhood ALL in second or greater remission or [refractory](#) ALL.

#### B. Adults

1. High dose chemotherapy with [allogeneic](#) or [autologous](#) stem cell support may be considered medically necessary as a treatment of adult ALL in first complete remission but at high risk of relapse. High risk of relapse following initial complete remission is indicated by the presence of at least **one** of the following:
  - a. Leukocyte count greater than  $10 \times 10^9/L$
  - b. Extramedullary disease, particularly CNS
  - c. Chromosomal abnormalities, including Philadelphia chromosome
  - d. Failure to achieve a complete remission within 6 weeks of the start of induction therapy.

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2. High dose chemotherapy with [allogeneic](#) stem cell support may be considered medically necessary as a treatment of adult ALL in second or greater remission, or in patients with relapsed or [refractory](#) ALL.
3. High dose chemotherapy with allogeneic stem cell support may be considered medically necessary as a treatment in adults with Progenitor-B cell ALL.

### When Bone Marrow Transplant for Acute Lymphocytic Leukemia is not covered

- High dose chemotherapy with [autologous](#) stem cell support is considered investigational as a treatment of adult ALL in second or greater remission or those with [refractory](#) disease.

### Policy Guidelines

- As noted above in the Description of Procedure or Service section, there is no clear age cut off that distinguishes adults from children with ALL.
- While some HDC protocols can be administered on an outpatient basis, typically the patient is hospitalized for management of the marrow ablative complications of the therapy. All patients receiving whole body radiotherapy, typically those receiving an [allogeneic](#) transplant (from donor to patient), will require prolonged hospitalization.
- Refer to the individual certificate for prior approval/precertification requirements.

### Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 38205, 38206, 38230, 38240, 38241, 38242, S2150*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all [specific](#) information needed to make a medical necessity determination is included.

### Policy Key Words

Key Words: High Dose Chemotherapy, HDC, Stem Cell Support, SCS, Autologous, Allogeneic, Acute Lymphocytic Leukemia, ALL, Children, Childhood, Adult, Adults, Bone Marrow Transplant, BMT, SUR6090.3

### Medical Term Definitions

#### **Ablation**

the removal of tissue or an abnormal growth, usually by cutting; may also refer to a very high dose of treatment that is calculated to kill a tumor.

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### **Allogeneic**

genetically dissimilar - involves a donor and a recipient; genes are not identical in each organism.

### **Autologous**

derived from the same organism, i.e., self donation.

### **Cytotoxic agents**

drugs which possess a specific destructive action on certain cells; often used to refer to drugs used to fight cancer, such as chemotherapy.

### **Harvesting**

to remove tissues or cells from a donor and preserve for transplantation.

### **Hematopoietic**

pertaining to or effecting the formation of blood cells.

### **Histocompatible**

tissue compatible; donor and recipient are well enough matched that a transplant will be easily accepted.

### **Myelosuppressive**

something that inhibits bone marrow activity, resulting in decreased production of blood cells and platelets.

### **Opportunistic**

a microorganism that does not usually cause disease but that, under certain circumstances such as impaired immune system due to other diseases or drug treatment becomes pathogenic.

### **Placenta**

Temporary organ formed from both fetal and maternal tissues that provides nutrients and oxygen to the developing fetus, carries away fetal metabolic wastes, and produces the hormones of pregnancy.

### **Refractory**

not responding to treatment.

### **Steep dose response curve**

a theory in delivery of cytotoxic agents that small increments in dosage will result in relatively large increases in tumor cell kill.

### **Stem cells**

immature generic blood cells that will mature into the various types of blood cells in the body.

### **Umbilical cord**

a flexible structure through which the umbilical arteries and vein pass and which connects the fetus to the placenta.

## **Scientific Background and Reference Sources**

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TEC Assessment, January, 1998; Volume 12, No. 25

BCBSA Medical Policy Reference Manual, 4/30/2000

TEC Assessment, August, 2000; Volume 15, No. 9

## Policy: Bone Marrow Transplant for Acute Lymphocytic Leukemia

BCBSA Medical Policy Reference Manual, 8/18/2000

Specialty Matched Consultant Advisory Panel - 11/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.32, 12/18/02

Specialty Matched Consultant Advisory Panel 11/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.32, 9/27/05

Specialty Matched Consultant Advisory Panel - 3/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.32, 4/17/07

Specialty Matched Consultant Advisory Panel - 3/2008

### Policy Implementation/Update Information

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- 1/01 Specialty Matched Consultant Advisory Group.
- 2/01 Original policy issued.
- 2/03 Specialty Matched Consultant Advisory Panel review 11/2002. No change in criteria. Codes 86812-86822 removed; codes 38231 and 86915 deleted and codes 38242, 38205 and 38206 added to the Billing/Coding section. System coding changes.
- 1/04 Benefits Application and Billing/Coding sections updated for consistency.
- 2/04 Individual CPT codes listed for CPT ranges 38240-38242 under Billing/Coding section.
- 7/29/04 Added code S2150 to the Billing/Coding section of the policy.
- 12/9/04 Specialty Matched Consultant Advisory Panel review 11/29/2004. No changes to criteria. Revised Description of Procedure or Service section. Reformatted When Bone Marrow Transplant for Acute Lymphocytic Leukemia is covered section. Wording revised under When Bone Marrow Transplant for acute Lymphocytic Leukemia is not covered. Added policy number to Policy Key Words section. "Hematopoietic" and "Opportunistic" added to Definitions. References added.
- 4/10/06 Specialty Matched Consultant Advisory Panel review 3/15/2006. Added to the "When covered" section an additional indication; "3. High dose chemotherapy with allogeneic stem cell support may be considered medically necessary as a treatment in young adults with Progenitor-B ALL". References added.
- 6/2/08 Specialty Matched Consultant Advisory Panel review 3/17/08. Added reference to the Clinical Trials policy to the "Policy" section. Removed from the "When Not Covered" section; "High dose chemotherapy and allogeneic stem cell support is considered investigational for children and adults, as a treatment of relapsing ALL after a prior course of high-dose chemotherapy and autologous stem cell support." References added.

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

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